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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,878	09/26/2003	Jennie P. Mather	415072000101	9515

25226 7590 03/25/2005

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,878	MATHER ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *7 and 18-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6,8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed on 2/23/04 is acknowledged.
Specification has been amended accordingly.

2. Claims 1-27 are pending.

Applicant's election without traverse of Group I, claims 1-17 drawn to a method for producing monoclonal antibodies with the elected species of RL-65 and fibronectin in the reply filed on 2/25/05 is acknowledged.

Claims 7, 18-27 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions/species.

Claims 1-6, 8-17 are under consideration in the instant application.

3. Sequence compliance: The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

5. Applicant's IDS filed on 12/12/03 is acknowledged. However, non-patent literatures IDS references 7-36, and 38-46 have not been considered. Parent cases 09/218,539 and 09/614,483 have been reviewed and the references are not available. Applicant is required to provide copies of non-patent literatures for consideration.

6. It is noted that "Table II" is missing from the specification of the instant application (p.28, lines 19, 23, and 30) and the description of Figure 9 on p.32 (lines 5, 6, 9, 10 and 13, recitation of A2, A1, A3, C1 and C2) of the instant application does not match with the Figure 9.
Appropriate correction is required.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2-6, 8-17 are ambiguous in the recitation of "the cells". The base claim 1 contains more than one type of cells.

9. Claim 17 is indefinite for reciting "functional effect" because the metes and bounds of this functional effect are unclear and ambiguous.

10. Claim 10 is indefinite in the recitation of ASC, ESC, ROG, BUD, RED, NODD, BR516, RL-65 and NEP because their characteristics are not known. The use of ASC, ESC, ROG, BUD, RED, NODD, BR516, RL-65 and NEP cell lines as the sole means of identifying the claimed cell lines renders the claims indefinite because ASC, ESC, ROG, BUD, RED, NODD, BR516, RL-65 and NEP are merely laboratory designations which do not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct cell lines.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The cell lines recited in claim 10, ASC, ESC, ROG, BUD, RED, NODD, BR516, RL-65 and NEP are essential to the claimed invention. The reproduction of the cell lines is an extremely unpredictable event. The cell lines ASC, ESC, ROG, BUD, RED, NODD, BR516, RL-65, and NEP, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the cell lines, and it is not apparent if the cell lines are readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a

position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the cell lines have been deposited under the Budapest Treaty **and that the cell lines will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808**. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent whichever is longer.** See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the cell lines described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-6, 8-11, 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okabe (Cancer Res., 1984, 44:5273-5278, IDS reference 37) in view of Mather et al. (U. S. Pat. No. 5,364,785, IDS reference 1).

Okabe et al. teach a method for producing monoclonal antibodies that bind to antigens that are heterologous to a host mammal (i. e. human small cell carcinoma cells of the lung to a BALB/c mice, abstract, and material and methods, p. 5273), immunizing the host, fusing lymphoid cells, culturing hybridoma and selecting the hybridoma by immunoassay (p. 5273, col. 2, radioimmunoassay), cell sorting process (FACS) (abstract, p. 5274, col. 1, 1st paragraph) and functional effect (complement-mediated cell lysis) of antibody (p.5274 col.1, 2nd paragraph).

Okabe et al. further teach the antigen is on the surface membrane (abstract), and the origin of the cells are embryonic, and endodermic (p. 5278, discussion).

The claimed invention differs from the reference teachings by using the intact cells (RL-65) grown in the serum free media, morphology of cells and biological substrate.

However, Mather et al. teach the isolation of a single epithelial cell type from lung tissue (col. 2, lines 64-68). Mather et al. further teach a method of isolating an epithelial lung cell line (RL-65) in the serum free media (col. 2-3 overlapping paragraph), immortalized (i.e. grow over 2 yrs in continuous culture col. 2, lines 20-22), the cell line is suitable for homologous protein production, heterologous protein expression (i.e. cell specific antigent, col. 4, lines 61-69 and col. 5, lines 1-6), cell growth in the form of monolayer (col. 7, lines 33-36), aggregates (i.e. colony, col. 7, lines 33-36), and on a fibronectin substrate (col. 7, lines 30-32).

Mather et al. also teach the functions of lungs have been difficult to study *in vitro* because of diverse cell types (col. 1, lines 25-31, col. 2, lines 61-69).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ an isolated epithelial cell line RL-65 taught by Mather et al. in the monoclonal antibody generation method taught by Okabe et al.

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because the generation of epithelial cell specific monoclonal antibodies would be provided to study lung endocrinology and physiology as taught by Mather et al.

From the combined teachings of references, one of the ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence to the contrary.

15. Claims 1 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okabe (Cancer Res., 1984, 44:5273-5278, IDS reference 37) in view of Mather et al. (U. S. Pat. No. 5,364,785, IDS reference 1) and Sharp et al. (U.S.Pat. No. 4,487,829).

Teachings of Okabe et al. and Mather et al. have been discussed, supra.

The claimed invention differs from the reference teachings by using ELISA for selection.

However, Sharp et al. teach using ELISA assay as a diagnostic and therapeutic tool due to specific reactivity of monoclonal antibody to antigenic determinants (abstract, claim 9).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ an ELISA taught by Sharp et al. as a selecting tool in the monoclonal antibodies generated by a method taught by Okabe et al. and Mather et al.

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because the ELISA assay allows to select a monoclonal antibody of interest.

From the combined teachings of references, one of the ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence to the contrary.

No claims are allowable.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
March 15, 2005

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600
March 15, 2005